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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROLFE TYSON GUSTUS, CORBETT W. STONE, MICHAEL F. HOEY, ARTHUR G. BLANCK, LEN BRIGGS, MIKE PERRY, MEITAL MAZOR, and LINAS R. KUNSTMANAS

Appeal 2014-007428
Application 12/564,268
Technology Center 3700

Before LYNNE H. BROWNE, ERIC C. JESCHKE, and PAUL J. KORNICZKY, *Administrative Patent Judges*.

KORNICZKY, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF CASE

Appellants, Rolfe Tyson Gustus et al.,[1] appeal under 35 U.S.C. § 134 from the Examiner's decision rejecting claims 1, 4–12, 15–22, 26–41, 43, and 45–47.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify Vessix Vascular, Inc. as the real party in interest. Appeal Br. 4.

[2] Claims 2, 3, 13, 14, 23–25, 42, and 44 are cancelled. Appeal Br. 17–24 (Claims App.).

THE CLAIMED SUBJECT MATTER

The claims are directed to medical devices for inducing desirable temperature effects on body tissue using alternate energy sources. Claims 1, 12, 22, 26, and 33 are independent. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A system for inducing desirable temperature effects on body tissue, the body tissue being disposed about a blood vessel, the system comprising:
>
> an elongate catheter having a proximal end and a distal end with an axis therebetween;
>
> an inflatable balloon positioned adjacent to the distal end of the elongate catheter;
>
> an energy delivery portion including at least one ultrasound transducer or microwave antenna mounted to an outer surface of the inflatable balloon;
>
> a tissue analyzer configured to characterize the body tissue disposed about the blood vessel proximate the energy delivery portion;
>
> an energy source coupled to the energy delivery portion transmitting tissue treatment energy, wherein the energy is non-RF energy, wherein the energy source comprises microwave or ultrasound energy; and
>
> a processor coupled to the tissue analyzer and energy source, the processor configured to determine an appropriate treatment energy for the characterized body tissue by selecting an energy wavelength of the respective microwave or ultrasound energy based on characterization of the body tissue such that application of the appropriate treatment energy mildly heats the body tissue with the energy delivery portion without ablating the body tissue.

REFERENCES

In rejecting the claims on appeal, the Examiner relied upon the following prior art:

Klopotek	US 5,230,334	July 27, 1993
Neilson	US 5,330,518	July 19, 1994
O'Boyle	US 5,609,606	Mar. 11, 1997
Tu	US 6,036,689	Mar. 14, 2000
Driscoll	US 6,083,159	July 4, 2000
Houser	US 6,632,196 B1	Oct. 14, 2003
Cooper	US 2004/0220556 A1	Nov. 4, 2004
Mioduski	US 2005/0015125 A1	Jan. 20, 2005
Steinke	US 2005/0251116 A1	Nov. 10, 2005
Demarais	US 2007/0135875 A1	June 14, 2007
Wasicek	US 7,245,959 B1	July 17, 2007

REJECTIONS

The Examiner made the following rejections:

1. Claims 1, 4, 9–12, 15, 20, and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinke and Tu.

2. Claims 5–8 and 16–19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinke, Tu, and Cooper.

3. Claim 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinke, Tu, and Neilson.

4. Claims 26, 28, 30–33, 35, and 37–40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinke, Tu, Cooper, and Driscoll.

5. Claims 27 and 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinke, Tu, Cooper, Driscoll, and Neilson.

6. Claims 29 and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinke, Tu, Cooper, Driscoll, and Mioduski.

7. Claim 41 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinke, Tu, Cooper, Driscoll, and Klopotek.

8. Claim 43 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinke, Tu, Cooper, Driscoll, Klopotek, and Demarais.

9. Claim 45 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinke, Tu, and O'Boyle.

10. Claims 46 and 47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinke, Tu, Houser, and Wasicek.

11. Claim 12 stands rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1, respectively, of copending Application No. 11/975,651 and Steinke.

Appellants seek our review of these rejections.

ANALYSIS

The Rejection of Claims 1, 4, 9–12, 15, 20, and 22 As Unpatentable over Steinke and Tu

Appellants argue claims 1, 4, 9–12, 15, 20, and 22 as a group. Appeal Br. 9–11. We select claim 1 as the representative claim, and claims 4, 9–12, 15, 20, and 22 stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner finds that Steinke discloses all of the limitations of claim 1, except "Steinke fails to teach that the microwave/ultrasound energy delivery portion is mounted to an outer surface of an inflatable balloon." Final Act. 6–7. The Examiner finds that this missing limitation is taught by Tu, and determines that it would be obvious "to utilize expandable electrodes located onto and around a balloon, as taught by Tu, with the

system and method of Steinke in order 'to apply appropriate pressure to ensure intimate tissue contact.'" Final Act. 8 (citing Tu, 3:49–50).

In response, Appellants assert several times that the combination of Steinke and Tu is improper, and reassert the reasons "presented in the response filed July 23, 2013" (called App. Resp.). Appeal Br. 10. First, Appellants argue that "[n]owhere do Steinke et al. appear to disclose or suggest that a balloon should include an energy delivery portion mounted thereto." App. Resp. 10. However, the Examiner's finding states that Tu, not Steinke, discloses "expandable electrodes located onto and around a balloon." Final Act. 8. Appellants' argument does not respond to the rejection as articulated by the Examiner and, thus, does not identify Examiner error.

Second, Appellants argue that Tu's teachings may not be incorporated into Steinke because the proposed combination renders Steinke's device "incapable of functioning as intended." App. Resp. 11–12; *see also* Appeal Br. 13 ("the modification proposed by the Examiner would at least change a principle of operation of the Steinke et al. device if not completely render the Steinke et al. device unsatisfactory for its intended purpose."). Appellants assert that because (1) Steinke uses "rotating optical conduits to transmit and/or direct imaging light and ablating light through a distal portion of a catheter system towards a vessel wall," and (2) Steinke's "imaging light and the ablative light may run through the same optical conduits," Tu's metallic electrodes "are incapable of transmitting optical energy for either imaging or ablation, as required by Steinke et al." App. Resp. 11; *see also* Appeal Br. 10–11; and Reply Br. 2.

In response, the Examiner correctly finds that Steinke is not limited to imaging and ablation utilizing optical energy, and explicitly teaches that ultrasonic energy may be used, as recited in claim 1. Final Act. 3 (citing Steinke ¶ 123); *see also* Ans. 3 (citing Steinke ¶ 123, which states "a wide variety of mechanical, thermal, optical, ***ultrasonic*** or chemical working elements for treating atherosclerotic material . . . might be employed ***in place of*** or in combination with the ablative laser energy described above."). The Examiner further explains that, "[a]s pointed out by the Applicant, 'One of ordinary skill in the art would recognize that neither a balloon nor a basket of electrode members disposed about a balloon should be rotated within a vessel lumen.'" Final Act. 3 (citing to App. Resp. 12). Citing to Steinke's teachings, the Examiner also explains that

> if ultrasonic work elements replaced the ablative laser energy embodiment, that "those of skill in the art will recognize that a variety of modification, adaptations, and changes may be employed *(see* [Steinke] paragraph 123)." These modifications, adaptations and changes would *obviously* include the removal of optical channels with the replacement of wiring and other necessary system changes to provide ultrasonic ablative energy.

Ans. 3–4.

With respect to Appellants' argument that, if ultrasound or microwave were used in place of optical energy, Steinke would be unable to transmit optical light for imaging through the same lumen, the Examiner correctly finds that Steinke teaches that separate optical conduits may be used. Ans. 5 (citing Steinke ¶ 110); *see also* Steinke ¶ 112 ("[T]he same optical conduit can be used to carry both imaging and ablating light. In other preferred embodiments, two different optical conduits can be used to carry the imaging light and the ablating light.").

Here, Appellants do not show that the Examiner's proposed modification is beyond the skill of one skilled in the art. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) ("The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. . . . Rather, the test is what the combined teaching of those references would have suggested to those of ordinary skill in the art."); *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond [his or her skill]."). Thus, Appellants do not apprise us of error.

Third, using an incomplete and misleading quote, Appellants also argue that, due to mechanical trauma which may be caused by balloon dilation, Steinke "teach[es] away from the use of the balloon-supported basket-type electrodes like those taught by Tu et al." Appeal Br. 10–11.[3]

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[3] The entire quote from Steinke states:

> *Ablative laser energy can then be selectively and automatically directed to the appropriate plaque structures,* ***often*** without imposing mechanical trauma to the entire circumference of the lumen wall generally associated with balloon dilation, stenting, and known atherectomy methods.

Steinke ¶ 15 (italics identifies language missing from Appellants' quote; emphasis added). As the Examiner correctly notes, Appellants eliminated the word "often" and reference to ablative laser procedures, and this sentence does not indicate that all tissue contact is always unacceptable.

However, to teach away, a reference's disclosure must "criticize, discredit or otherwise discourage the solution claimed." *In re Fulton*, 391 F.3d 1195, 1199–1201 (Fed. Cir. 2004). The Examiner correctly finds that the use of balloon dilation, despite the alleged mechanical trauma, is disclosed throughout Steinke. Ans 5 (citing Steinke ¶ 53 (The "embodiments of the present invention may be used in combination with stenting and/or balloon dilation.")); *see also* Final Act. 7; and Steinke ¶ 58, 65, 66, and 79. We are not persuaded that Steinke teaches away from the proposed combination.

Finally, Appellants argue that "[n]owhere do Tu et al. appear to disclose or suggest that the balloon-supported basket-type electrodes provide selective, eccentric ablation without damaging the healthy area of the tissue, as disclosed by [Steinke]." Appeal Br. 11; *see also id.* at 14. However, the Examiner relied on Steinke, not Tu, for teaching the use of balloons. Final Act. 7–8; *see also* Ans. 4. Tu also discloses that "intimate tissue contact" with the electrode-mounted balloon is acceptable. Final Act. 8 (citing Tu 3:49–50). Appellants' argument does not respond to the rejection as articulated by the Examiner and, thus, does not identify Examiner error.

For the reasons discussed above, we sustain the rejection of claim 1, and claims 4, 9–12, 15, 20, and 22 fall with claim 1.

The Rejections of Claims 5–8, 16–19, 21, and 45–47

In response to the rejections of claims 5–8, 16–19, 21, and 45–47, which depend from independent claims 1, 12, or 22, Appellants argue that (1) these dependent claims include the features of the independent claims

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Ans. 5–6. In this regard, Tu discloses that "intimate tissue contact" with the balloon is acceptable. *See, e.g.*, Tu 3:49–50.

from which they depend, and are patentable for the same reasons, and (2) these dependent claims "also include further distinguishing features." Appeal Br. 11–13. For the reasons discussed above, the rejections of claims 1, 12, and 22 are sustained over the cited prior art. Because Appellants do not identify any patentable features of these dependent claims over claims 1, 12, and 22, we sustain the rejections of claims 5–8, 16–19, 21, and 45–47.

The Rejection of Claims 26, 28, 30–33, 35, and 37–40 As Unpatentable over Steinke, Tu Cooper, and Driscoll

Appellants argue claims 26, 28, 30–33, 35, and 37–40 as a group. Appeal Br. 13–14. We select claim 26 as the representative claim, and claims 28, 30–33, 35, and 37–40 stand or fall with claim 26. 37 C.F.R. § 41.37(c)(1)(iv).

With respect to the rejection of claim 26, Appellants essentially repeat their arguments against the rejection of claim 1 — as "discussed above with respect to claim 1, there is no appropriate motivation to combine the teachings of Steinke et al. and Tu et al."[4] and that "the modification proposed by the Examiner would at least change a principle of operation of the Steinke et al. device if not completely render the Steinke et al. device unsatisfactory for its intended purpose." Appeal Br. 13. Repeating their argument with respect to claim 1, Appellants also argue that "Steinke et al. appear to teach away from the use of the balloon-supported basket-type

[4] The Examiner, for example, reasons that it would have been obvious "to utilize expandable electrodes located onto and around a balloon, as taught by Tu, with the system and method of Steinke in order 'to apply appropriate pressure to ensure intimate tissue contact (see [Tu] column 3, lines 49-50).'" As discussed with respect to claim 1, the Examiner's articulated reasoning has a rational underpinning. *KSR*, 550 U.S. at 418.

electrodes like those taught by Tu et al." Appeal Br. 13–14. As we find no error in the rejection of claim 1, Appellants' arguments are unpersuasive and the rejections of claims 26, 28, 30–33, 35, and 37–40 are sustained.

The Rejections of Claims 27, 29, 34, 36, 41, and 43

In response to the rejections of claims 27, 29, 34, 36, 41, and 43, which depend from independent claims 26 or 33, Appellants argue that (1) these dependent claims include the features of the independent claims from they depend, and are patentable for the same reasons, and (2) these dependent claims "also include further distinguishing features." Appeal Br. 14–15. As we find no error in the rejections of claims 26 and 33 and because Appellants do not identify any patentable features of the dependent claims over claims 26 and 33, Appellants' arguments are unpersuasive and we sustain the rejections of claims 27, 29, 34, 36, 41, and 43.

The Doubling Patenting Rejection of Claim 12

In response to the Examiner's rejection, Appellants merely state that "[c]laims 1 and 12 are patentable over claims 1, 16, and 24 of U11/975,651 in view of Steinke et al. (U.S. Patent Pub. No. 2005/0251116) because the claims of the cited application, with or without the teachings of Steinke et al., do not render obvious the pending claims." Appeal Br. 15–16. Because Appellants do not address the substance of the rejection, we summarily sustain the rejection.

DECISION

For the above reasons, the Examiner's rejections of claims 1, 4–12, 15–22, 26–41, 43, and 45–47 are AFFIRMED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED